

24. The composition of claim 17 wherein the influenza virus vaccine and the mucosal adjuvant composition are intended for administration as a nasal spray.

25. The composition of claim 17 wherein the influenza virus vaccine and the mucosal adjuvant composition are intended for administration as a nasal drops.

IN THE ABSTRACT:

Replace the existing abstract with the following:

Adjuvant for mucosal vaccines which enhances the effects of substances, including vaccine antigens in contact with mucosal body surfaces.

REMARKS

The Applicants appreciate the attention of the Examiner to the application. This application has been carefully reviewed and this Preliminary Amendment prepared in view of the Examiner's comments in the Office Action dated February 20, 2001 and the Advisory Action issued July 18, 2001.

The amendments to the specification are made to simply correct typographical and grammatical errors. No new matter is added. The amendments to the title and the abstract are for the purpose of maintaining consistency with claim 1, as amended. As discussed below, such amendments do not add new matter or introduce new issues.

The Rejections

In the Office Action of February 20, 2001, the Examiner rejected claims 1, 2, 4-8 and 13 under 35 U.S.C. § 102(b) as being anticipated by the Benach et al. publication. Claims 1, 2, 4-8 and 13 were also rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,641,761 (Takahashi et al.). Claims 2-8 and 13 were rejected under 35 U.S.C. § 112, second paragraph, in that there is no antecedent basis for the term "substance."

### Analysis of the Claims

As described on page 4, lines 33-35 of the specification, claim 1, as amended, is directed to a mucosal adjuvant that enhances the effect of medicinal substances administered onto mucosal surfaces. Enhance means to “increase or improve in value, quality, desirability, or attractiveness.”<sup>1</sup> As such, the claim 1 is directed to a mucosal adjuvant composition that improves the effect of medicinal substances administered onto mucosal surfaces. Because the original specification described an adjuvant used “to enhance the ability of mucosal vaccine antigens,”<sup>2</sup> no new matter or issues are raised by amendment of claim 1.

Claim 1, as amended, also introduces the term “substance” thereby overcoming the rejection of claims 2-8 and 13 under 35 U.S.C. § 112, second paragraph. Claim 1, as amended, describes the structure of the mucosal adjuvant composition as one comprising a branched beta-1,3-glucan that contains beta-1,3-linked side chains anchored by a beta-1,6-linkage to the beta-1,3-linked chains. Such structure, which is described on pages 13 to 16 of the specification, is not disclosed in either the Benach et al. publication, which discloses a linear beta-1,3-glucan without side chains, or the Takahashi et al. patent where instead of side chains the main glucan chain has single glucose side groups. For this reason, the Applicants request that the Examiner withdraw the rejection of claims 1, 2, 4-8 and 13 under 35 U.S.C. § 102(b).

New claims 14-16 correct a indefiniteness problem that existed in original claims 7 and 8 in that they eliminate the use of the conjunction “or.”

New claim 17 incorporates the limitation of original claim 3 into claim 1. Since claim 3 was rejected solely under 35 U.S.C. § 112, second paragraph, in that the term “substance” lacked

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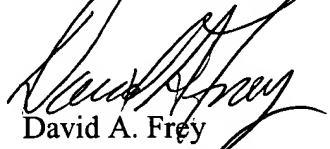
<sup>1</sup> *Merriam-Webster's Collegiate Dictionary*, (12<sup>th</sup> ed.) 384.

<sup>2</sup> Page 4, lines 33-35 of the specification.

an antecedent basis, new claim 17 and its dependent claims 18-25 should be allowed as such term "substance" does not appear within any of the claims.

This application is believed to be in condition for allowance and early favorable action is requested. The Examiner is requested to call the under-signed attorney if that would be helpful in resolving any minor matter which might remain.

Respectfully submitted,

  
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE:

Delete the word “MODULATES” and replace with –ENHANCES--.

IN THE SPECIFICATION:

On page 2, line 12, insert a comma --,-- following the word administration and before the word the.

On page 2, line 16, insert a comma --,-- following the word administration and before the word as.

On page 2, line 14, delete “tradiditional” and insert –traditional--.

On page 5, line 13, delete “exicipients” and insert –excipients--.

On page 5, line 14, delete “diphtheria” and insert –diphtheria--.

On page 5, line 15, delete “aluminium” and insert –aluminum--.

On page 7, line 18, following the word simultaneously insert the word –with--.

On page 13, line 23, insert a comma -- , -- following the word nasally and before the word rectally.

IN THE CLAIMS:

1. (Twice amended) A mucosal adjuvant composition that enhances the effect of medicinal substances administered onto mucosal surfaces, the mucosal adjuvant composition comprising a branched beta-1,3-glucan that contains beta-1,3-linked side chains anchored by a beta-1,6-linkage to the beta-1,3-linked chains [a glucose monomers linked together in branched beta-1,3 linked chains with beta–1,3,6 linked branching points comprising beta-1,3 linked or beta 1,6 linked side chains].

6. (Amended) The composition of claim 1 wherein the substance is mixed with the mucosal adjuvant [preparation] composition.

7. (Amended) The composition of claim 1 wherein the substance administrated prior to[, simultaneously with or after] the mucosal adjuvant preparation.

8. (Amended) The composition of claim 1 wherein the substance and the mucosal adjuvant preparation are intended for administration as nasal spray [or nasal drops].

IN THE ABSTRACT:

Delete the word “modulates” and replace with –enhances--.